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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/572,945	12/11/2006	Kazumi Yagasaki	288272US0PCT	7649

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EXAMINER	
VAKILI, ZOHREH	
ART UNIT	**PAPER NUMBER**
1614	

NOTIFICATION DATE	DELIVERY MODE
03/31/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/572,945	YAGASAKI ET AL.	
	Examiner	Art Unit	
	ZOHREH VAKILI	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *622/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-5 are presented for examination.

Set of claims under examination: a component or composition for inducing apoptosis in hepatoma cells, characterized in that the component or composition contains enterolactone or plant lignan precursor compounds of thereof as active ingredients.

Claim Objection

Claim 5 objected to because of the following informalities: Period is missing at the end of the sentence. Appropriate correction is required.

LACK OF WRITTEN DESCRIPTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH:

Claims 1-5 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification discloses chemicals, such as enterolactone or plant lignan, which meet the written description and enablement provisions of 35 USC 112, first paragraph.

However, claims 1-5 are directed to encompass precursor, which only correspond in some undefined way to specifically instantly disclosed chemicals. None of these precursors, meet the written description provision of 35 USC § 112, first paragraph, due to lacking chemical structural information for what they are and chemical structures are highly variant and encompass a myriad of possibilities. The specification provides insufficient written description to support the genus encompassed by the claim.

Vas-Cath, Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.* (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116).

With the exception of the above specifically disclosed chemical structures, the skilled artisan cannot envision the detailed chemical structure of the encompassed derivatives, analogs, etc., regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The chemical structure itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification

provided only the bovine sequence. Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

> …To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.,* 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli,* 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.

Therefore, only the above chemically structurally defined chemicals, but not the full breadth of the claim(s) meet the written description provision of 35 USC § 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC § 112 is severable from its enablement provision. (See page 1115).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Ahotupa et al. (US Pub. No. 2002/0061854 A1) (cited on IDS) and in view of Pezzuto et al. (US Pat. No. 6008260).

Ahotupa et al. discloses methods for prevention of **cancers**, certain non-cancer, hormone dependent diseases and/or cardiovascular diseases in a person, based on administering of hydroxymatairesinol to said person. The invention also concerns a method for increasing the level of **enterolactone** or another metabolite of

hydroxymatairesinol in a person's serum thereby causing prevention of a cancer or a certain non-cancer, hormone dependent disease in a person, based on administering of hydroxymatairesinol to said person. Furthermore, this invention relates to pharmaceutical preparations, food additives and food products comprising hydroxymatairesinol (see abstract). Lignans are defined as a class of phenolic compounds possessing a 2,3-dibenzylbutane skeleton. They can be found in different parts (roots, leafs, stem, seeds, fruits) but mainly in small amounts. In many sources (seeds, fruits) lignans are found as glycosidic conjugates associated with fiber component of plants. The most common dietary sources of mammalian lignan precursors are unrefined grain products. The highest concentrations in edible plants have been found in flaxseed, followed by unrefined grain products, particularly rye [0003]. Plant lignans such as matairesinol and secoisolariciresinol, are converted by gut microflora to mammalian lignans, **enterolactone and enterodiol** correspondingly [0007]. To increase lignan intake has been to increase the consumption of fiber-rich food items such as flaxseed. Lignan that is efficiently converted to enterolactone can be produced/isolated in large quantities would be valuable in the development of **pharmaceutical preparations** and **food products such as functional foods** for chemoprevention of cancer and other hormone-related diseases and cardiovascular diseases [0011]. The invention concerns a pharmaceutical preparation comprising an effective amount of hydroxymatairesinol in combination with a **pharmaceutically acceptable carrier [0014]**. The invention concerns a product comprising a liquid or solid material enriched with hydroxymatairesinol for use as additive to a food product

[0015]. The method according to this invention is particularly effective in the prevention of cancers such as breast cancer, prostate cancer and colon cancer [0024]. The food product according to this invention is especially a functional food, a nutritional supplement, a nutrient, a pharmafood, a nutraceutical, a health food, a designer food or any food product. [0029].

Pezzuto et al. teach a method of chemopreventing cancer comprising administering a cancer chemopreventative composition to a mammal in need thereof in a sufficient amount to suppress the initiation, promotion, or progression of a cancer said cancer selected from the group consisting of a mammary cancer, a skin cancer, human leukemia, a hepatoma, a colon cancer (see claim 1).

The primary reference teaches treatment of cancers, however it does not teach hepatoma as indicated by the secondary reference hepatoma is a type of cancer.

It would have been obvious to have combined the teachings of the above mentioned references since the primary reference teaches all the components of the claimed invention to treat cancer broadly. The secondary reference teaches hepatoma being a type of cancer.

One would have been motivated to create such formulation because Ahotupa et al. teaches all the component of the claimed invention only to treat cancer broadly. Pezzuto et al. teaches hepatoma is type of cancer. Therefore, one of ordinary skill in the art would have been motivated to use the preparation of Ahotupa et al. to develop a formulation to treat hepatoma. It will be apparent to one of ordinary skill in the art that

many changes and modifications can be made thereto without departing from the spirit or scope of the appended claims.

Finally, one would have a reasonable expectation of success given that Ahotupa et al. provide a detailed blueprint for making the formulation to treat hepatoma, and the steps of which are routine to one of ordinary skill in the art.

Thus the claimed invention was within the ordinary skill in the art to make and use at the time the claimed invention was made and as a whole, prima facie obvious.

Conclusion

No claims of the present application are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zohreh Vakili whose telephone number is 571-272-3099. The examiner can normally be reached on 8:30-5:00 Mon.-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Zohreh Vakili

Patent Examiner 1614 March 16, 2010

/Ardin Marschel/

Supervisory Patent Examiner, Art Unit 1614